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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,787	08/14/2001	Edward J. Noga	5051-551	9013
20792	7590	03/02/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			ZEMAN, ROBERT A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,787

Applicant(s)

NOGA ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 10 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment and response filed on 11-3-2004 are acknowledged. Claim 9 has been canceled. Claims 1-4, 10 and 19 remain withdrawn from consideration. Claims 5-8 are currently under examination.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps is maintained for reasons of record.

Applicant argues:

1. The manner which antimicrobial activity is not critical since any technique can be used.
2. The manner in which peptides are isolated is not critical since any technique can be used.
3. The methods for isolation of peptides is well established and are known to skilled workers.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, Applicant's arguments are deemed persuasive since the determination of antimicrobial activity is not the critical to the patentability of Applicant's invention.

With regard to Points 2 and 3, it is unclear what Applicant is claiming as his invention since the stated goal of the claimed method is to isolate antimicrobial peptides from mast cells

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and Applicant has stated on the record that any isolation method may be used and that said isolation methods are well known in the art. Moreover, step c) recites the isolation of detected peptides (which is the stated goal of the claimed method) but no active steps are recited. Hence it is impossible to determine what isolation steps comprise the claimed “method of isolating an antimicrobial peptide”.

The rejection of claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record. Claim 5 is still confusing as it is unclear how one measures the antimicrobial activity of a given peptide (step b) before said peptide has been isolated. Moreover, the instant claims are drawn to methods of isolating antimicrobial peptides but fail to recite any active steps that constitute said method.

It should be noted that the previous Office action inadvertently referred to claim 5 as claim 9 in the rejection. However, it is clear by the body of rejection that claim 5 was being rejected as it is the only pending claim that recites a “step b)”.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 5-6 and 8 under 35 U.S.C. 102(b) as being anticipated by Robinette et al. (Cellular and Molecular Life Sciences Vo. 54, 1998, pages 467-475) in light of

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Abraham et al. (Infection and Immunity, Vol. 65, No. 9, pages 3501-3508) is maintained for reasons of record. The cancellation of claim 9 has rendered the rejection of said claim moot.

Applicant argues:

1. Robinette et al. is concerned with fish skin while Abraham et al. is concerned with mammalian skin. The two are not analogous.
2. While Robinette et al. describes antimicrobial peptides in fish skin, one would expect this activity to be associated with the mucous layer and associated secretory cells not with mast cells.
3. The cited references do not teach the step of “detecting a peptide having antimicrobial activity in said mast cells.

Applicant’s arguments have been fully considered and deemed non-persuasive.

The instant claims are drawn to methods of isolating antimicrobial peptides comprising providing mast cells where in said mast cells are optionally from fish, detecting a peptide having antimicrobial activity in said mast cells and isolating said peptides. The instant claims recite no active steps with regard to detecting said peptides or isolating said peptide.

Robinette et al. disclose the isolation of antimicrobial polypeptides from the skin of channel catfish *Ictalurus punctatus*. Said methods included the extraction of skin samples, fractionation of the resulting extracts and the testing of said fractions for antimicrobial activity (see pages 468-471). While, Robinette et al. do not explicitly disclose that the isolation of peptides from mast cells, said mast cells would be present in the skin samples used by Robinette et al. since mast cells are present in high concentrations in skin (see Abraham et al., page 3501 first and second paragraph) and Robinette et al. describe antimicrobial peptides in skin cells.

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Consequently, since Robinette discloses antimicrobial peptides in fish skin as well as methods that include the extraction of fish skin samples, fractionation of the resulting extracts and the testing of said fractions for antimicrobial activity, Robinette et al. anticipate all the limitations of the instant claims since peptides with antimicrobial activity would necessarily be in at least one of the fish skin fractions.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 5 and 7-8 under 35 U.S.C. 103(a) as being unpatentable over Selsted et al. (WO 94/21672) in view of Abraham et al. (Infection and Immunity, Vol. 65, No. 9,

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pages 3501-3508) is maintained for reasons of record. The cancellation of claim 9 has rendered the rejection of said claim moot.

Applicant argues:

1. There is no showing or teaching in the references that procedures for isolating antimicrobial peptides from neutrophils would also be applicable to mast cells.
2. Abraham et al do not disclose or teach microbicidal peptides from mast cells.

The instant claims are drawn to methods of isolating antimicrobial peptides comprising providing mast cells where in said mast cells are optionally mammalian mast cells, detecting a peptide having antimicrobial activity in said mast cells and isolating said peptides. The instant claims recite no active steps with regard to detecting said peptides or isolating said peptide.

Selsted et al. disclose methods of isolating antimicrobial peptides from bovine neutrophils. Said methods included the extraction of skin samples, fractionation of the resulting extracts and the testing of said fractions for antimicrobial activity (see Examples I-VII). Selsted et al. differs from the instant invention in that they do not explicitly disclose that the isolation of peptides from mast cells. Abraham et al. disclose the role mast cells play in infection and immunity. Specifically, they disclose that mast cells produce a number of antimicrobial polypeptides. Said peptides are contained in vacuoles and are involved in phagocytosis (see page 3504) or are excreted and act directly on the microbe (see page 3504). Consequently, it would have been obvious to one of ordinary skill in the art to utilize the methods disclosed by Selsted et al. to isolate antimicrobial polypeptides from mast cells. One would have had a high expectation of success since neutrophils and mast cells since both are phagocytic cells that share multiple

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features (see Table 2 of Abraham et al.). Therefore, the use of mast cells in the methods of Selsted et al. merely constitutes an obvious variation of the disclosed invention.

Moreover, since Selsted et al. disclose methods that include the extraction of mammalian skin samples, fractionation of the resulting extracts and the testing of said fractions for antimicrobial activity and Abraham et al. disclose mast cells are present in high concentrations in skin (see page 3501 first and second paragraph), the peptides with antimicrobial activity would necessarily be in at least one of the mammalian fish skin fractions. Consequently, the rejection is considered proper and is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866.

The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Zeman
February 23, 2005


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600